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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/125,635	08/21/98	MELTZER	P 4239-50420

HM12/0330

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EXAMINER	
BASI, N	
ART UNIT	**PAPER NUMBER**
1646	5

DATE MAILED: 03/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/125,635	Meltzer et al
Examiner	**Group Art Unit**
Nirmal. S. Basi	1646

☒ Responsive to communication(s) filed on *Aug 21, 1998* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-54* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-54* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825 within the statutory period set for response to this office action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

3. ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 12-13, drawn to a substantially purified polypeptide comprising SEQ ID Nos: 2, 3, 4 or 8, classified in class 530, subclass 350.

II. Claims 1-11, drawn to polynucleotide sequence comprising the encoded human A1B1, and cells comprising said polynucleotide, and DNA that hybridizes to said polynucleotide, classified in class 536, subclass 23.1, for example .

III. Claims 41 drawn to antibody classified in class 435, subclass 6, for example antibody, classified in class 530, subclass 387.9, for example.

IV. Claims 14-20, drawn to a method of identifying a candidate compound which inhibits estrogen receptor (ER)-dependent transcription comprising contacting the compound with the A1B1 polypeptide, classified in class 435, subclass 7.1 for example.

V. Claims 21, 26-27, drawn to method of screening a candidate compound which inhibits an interaction of A1B1 polypeptide with ER polypeptide in a cell, classified in class 435, subclass 7.21 for example.

VI. Claims 22-25 and 28-31, drawn to method of detecting an aberrantly proliferating cell in a tissue sample comprising determining the level of A1B1 gene expression, classified in class 435, subclass 6 for example.

VII. Claims 32-35, drawn to method of reducing proliferation of a cancer cell in a mammal comprising administering to the mammal a compound which inhibits expression of A1B1, wherein the compound reduces transcription of the DNA encoding A1B1 or translation of an A1B1 mRNA wherein translation is reduced using antisense DNA, classified in class 514, subclass 44 for example.

VIII. Claims 32, 36-40, and 53, drawn to method of reducing proliferation of a cancer cell in a mammal comprising administering to the mammal a compound which inhibits expression of A1B1, wherein the compound is A1B1 or a polypeptide comprising PAS domain, bHLH domain, ER-interacting domain, a peptide mimetic of A1B1 polypeptide, steroid receptor or nuclear co-factors, classified in class 514, subclass 2 for example.

IX. Claims 42-44, drawn to method of identifying a tamoxifen-sensitive patient, comprising contacting a patient with tamoxifen and determining the level of A1B1 gene expression, classified in class 800, subclass 8 for example.

X. Claims 45 and 47, drawn to transgenic animal wherein at least one copy of the A1B1 gene has been functionally deleted, classified in class 800, subclass 8 for example.

XI. Claims 46, drawn to transgenic animal wherein at least one copy of the pCIP gene has been functionally deleted, classified in class 800, subclass 8 for example.

XII. Claims 48-52, drawn to transgenic animal having more than one copy of A1B1 gene has been functionally deleted, classified in class 800, subclass 8 for example.

Claim 54 has not been grouped because it depends on claim 58, application does not contain a claim 58

The inventions are distinct, each from the other because of the following reasons:

The proteins of Invention I are related to the nucleic acids of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the encoded. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization.

The proteins of Invention I are related to antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementary of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists of the receptor protein.

The proteins Inventions I and the methods of Inventions IV, V, VI and VIII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins may be used for the production of antibodies of Invention III.

The nucleic acids of Invention II and the methods of Inventions V-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic can be used in hybridization assays, tissue typing or producing the encoded protein by *in vitro* transcription/translation.

The antibody of Invention III and the methods of Invention V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used in affinity purification of its related protein.

Invention I is distinct from the method of Invention VII wherein the product of Invention I can neither be used in nor made by the method of Invention VII.

Invention II is distinct from the method of Invention IV and VIII-IX wherein the product of Invention I can neither be used in nor made by the method of Invention IV and VIII-IX.

Invention III is distinct from the method of Invention IV and VI-IX wherein the product of Invention I can neither be used in nor made by the method of Invention IV and VI-IX.

Inventions X-XII are distinct from the method of Invention IV-IX wherein the product of Invention I can neither be used in nor made by the method of Invention IV- IX.

The methods of Inventions IV-IX are distinct from each other because they are independent, using separate method steps, active agents and having different effects.

The products of Inventions I-III and X-XII are distinct from each other because they are physically and functionally distinct chemical entities, and capable of separate use and manufacture.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-XII would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Thursday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
March 23, 2000

Gary L. Kunz

GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200